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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,869	05/04/2001	Ganapati R. Mauze	10010186-1	8374

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AGILENT TECHNOLOGIES, INC.
Legal Department
Intellectual Property Administration
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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,869

Applicant(s)

MAUZE ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9-14,16,18-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7,9-14,16,18-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Specification

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

All patents and publications mentioned herein, both *supra* and *infra*, are hereby incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

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Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 7, 9-14, 16, 18-20, and 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meade et al. (US Patent 5,952,172).
7. For purposes of examination, the limitation of "metal ion" has been construed as encompassing virtually any of the transition metals, and not simply nickel, zinc, and cobalt as found at page 5, first full paragraph, of the specification, and as recited in claim 10. Also, the aspect of the "metal ion that binds to the first complex" has been construed as encompassing both direct and indirect binding of the metal ion to the complex, wherein said indirect binding can encompass the "metal ion" being part of a second nucleic acid sequence that can also bind to one of the strands of the first complex.
8. Meade et al., teach at length a variety of methods by which electron donors and electron acceptors (electron transfer moieties) can be configured with nucleic acids. Column 7, third

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paragraph, provides an extensive list of both suitable transition metals and their ligands is provided.

9. Meade et al., column 7, penultimate paragraph, names a plethora of electron moieties that can be used, including zinc, cobalt, and nickel (limitations of claim 10). Also disclosed therein is the use of osmium and ruthenium (limitations of claim 9).

10. Meade et al., column 11, first full paragraph, states, "all combinations of electron donors and acceptors may be made..."

11. Meade et al., column 20, teach:

single stranded nucleic acid proceeds in several steps. First partial nucleic acid sequences are made, each containing a single electron transfer species, i.e. either a single transfer moiety or several of the same transfer moieties, using the techniques outlined above. Then these partial nucleic acid sequences are ligated together using techniques common in the art, such as hybridization of the individual modified partial nucleic acids to a complementary single strand, followed by ligation with a commercially available ligase.

12. As noted above, the aspect of using an "electron donor" and an "electron acceptor" on a first and second partial nucleic acid sequence is considered to meet the limitation of a) a probe that hybridizes to a target to form a first complex; and b) a metal ion that binds to the first complex.

13. Meade et al., column 20, also teaches that one or more electron donors and one or more electron acceptor may be added. And at column 21, second full paragraph, Meade et al., teach "it is to be understood that different species of electron donor and acceptor moieties may be attached to a single stranded nucleic acid. Thus, more than one type of electron donor moiety or electron acceptor moiety may be added to any single stranded nucleic acid."

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14. Meade et al., column 22, last paragraph, state “The choice of the specific electron donor and acceptor pairs will be influenced by the type of electron transfer measurement used...” Meade et al., column 23, Table 2, teaches explicitly of using “electronic initiation” so to produce detectable light, and that said light be the result of chemiluminescence, electrochemiluminescence, and/or electroluminescence. Meade et al., column 24, teach that application of an electrical potential to the electrically-conductive complex to produce a measurable light signal is a preferred embodiment. This teaching meets a limitation of claims 7, 11, 12, 16, 20, and 22-24.

15. In the event that the disclosure of Meade et al., does not anticipate the claimed invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have adapted the methods of Meade et al., such that transition metal-ligand complexes are designed and used in a method of detecting the presence of a target nucleic acid wherein a metal ion is added to the initial complex to produce an electrically conductive complex, and wherein the application of an electrical potential to the electrically conductive complex produces measurable light signal. In view of the detailed teaching of just such a method said ordinary artisan would have been highly motivated and would have had a most reasonable expectation of success.

16. For the above reasons, and in the absence of convincing evidence to the contrary, claims 7, 9-14, 16, 18-20, and 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 5,952,172 (Meade et al.).

Double Patenting

17. Claims 7, 9-14, 16, 18-20, and 22-24 of this application conflict with claims 7-20 of Application No. 10/892,928. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

18. Claims 7, 9-14, 16, 18-20, and 22-24 of this application conflict with claims 22-41 of Application No. 10/798,892. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

19. Claims 7, 9-14, 16, 18-20, and 22-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-20 of copending Application No. 10/892,928 in view of US Patent 5,952,172 (Meade et al.). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the method of claims 7-20 of the '928 application the aspect of using one or more electron donors and acceptors as disclosed by Meade et al., and that through the application of an

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electrical potential a measurable signal is produced wherein said the measurable signal is chemiluminescent or electrochemiluminescent.

This is a provisional obviousness-type double patenting rejection.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

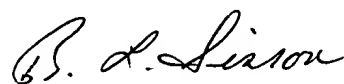
The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
13 May 2005